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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,668	04/21/2004	Igor Waysbeyn	H308-001-PAT	4917

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

NOTIFICATION DATE	DELIVERY MODE
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11/19/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipmail@eckertseamans.com

Office Action Summary	Application No. 10/828,668	Applicant(s) WAYSBEYN ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

It is noted that this application appears to claim subject matter disclosed in prior Application No. 60/493,764, filed August 11, 2003. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not

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extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Response to Arguments

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Applicant's arguments with respect to claims 11, 13, 15-24, and 26-28 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 37-39, 41-43, and 45-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Tanner et al. (US 6,635,066 B2). Tanner discloses a vascular device (see fig.4) comprising a stentless tubular graft (110), a first docking head (100) that's conical having a lumen (lumen at top end of cone and of 152) with a diameter the same as the graft, a second docking head ((20, 200) that's conical having a lumen (lumen of 22) with a diameter the same as the graft, wherein the docking heads are *adapted* to be adjusted along the graft prior to insertion into the vessel (the docking heads are separate structures from the graft and are *capable* of being attached before or after insertion), and wherein the docking heads have a plurality of outwardly pointing barbs (fasteners; 510, or 540 for example) that are inclined towards a longitudinal direction of the graft (see fig.32c, 32e). Tanner discloses the docking heads fastened to the graft by the claimed fasteners (col.10, lines 15-22). Tanner shows corresponding diameters in the figures. Tanner shows the barbs to have concave and convex curvatures (see fig.32e for example).

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In the alternative to the above rejection, claims 37-39, 41-43, 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner et al. (US 6,635,066 B2) in view of Weadock (US 2004/0225351 A1) or Baker et al. (US 2002/0091439 A1, cited previously). Tanner discloses a vascular device (see fig.4) comprising a stentless tubular graft (110), a first docking head (100) that's conical having a lumen (lumen at top end of cone and of 152) with a diameter the same as the graft, a second docking head ((20, 200) that's conical having a lumen (lumen of 22) with a diameter the same as the graft, wherein the docking heads are *adapted* to be adjusted along the graft prior to insertion into the vessel (the docking heads are separate structures from the graft and are *capable* of being attached before or after insertion), and wherein the docking heads have a plurality fasteners for attaching to the vessel wall. Tanner discloses any suitable fastener may be used, however does not disclose the specific fastener claimed (inclined barbs). Both Weadock and Baker teach alternate fasteners for graft structures for attaching to the vessel wall (28, 30 of Weadock and 195 of Baker). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Tanner's vascular structure having fasteners with Weadock or Bakers teaching of alternate fasteners (inclined barbs) in order to fasten the device to the vessel wall as the taught fasteners are obvious alternatives or equivalents to Tanner's fasteners.

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Claims 51-53, 55-57, and 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (US 2004/0225351 A1) in view of Tanner et al. (US 6,635,066 B2). Weadock discloses a vascular device comprising a stentless bifurcated graft (10), a first docking head (20) at the proximal end of the graft, and second docking and third heads (50, 52) at the distal ends of the graft. Weadock does not disclose the exact structure of the docking heads claimed (conical). Tanner teaches in the same field of vascular devices, conical barbed docking head structures (20) that seal and secure the graft to the vessel wall, the conical taper provides increased surface area with the vessel to improve the seal (col.9, lines 60-62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute Weadock's docking heads with those of Tanner, as they are an obvious alternative for sealing grafts to vessel walls.

Claims 37-39, 41-47, and 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliot (US 2003/0236567 A1, cited previously) in view of Weadock (US 2004/0225351 A1) or Baker et al. (US 2002/0091439 A1, cited previously). Elliot discloses a vascular device (see fig.3a-3c) comprising a stentless tubular graft (12; a stent may or may not be used; P0020, P0021), a first docking head (16+22) that's conical having a lumen (lumen at top end of cone) with a diameter the same as the graft, a second docking head (multiple docking heads, P0026) that's conical having a lumen (bottom end of cone) with a diameter the same as the graft, wherein the docking heads are *adapted* to be adjusted along the graft prior to insertion into the vessel (the docking heads are separate structures from the graft and are *capable* of being attached before or after insertion). Elliot discloses the vascular device substantially as claimed, however does not disclose inclined barbs on the docking heads. Both Weadock and Baker teach

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inclined barbs on vascular devices for attaching/fastening the graft to the vessel wall (28, 30 of Weadock and 195 of Baker). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Elliot's vascular structure with Weadock or Bakers teaching of inclined barbs on vascular devices in order to better fasten the device to the vessel wall.

Claims 51-53, 55-61 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (US 2002/00225351 A1) in view of Elliot (US 2003/0236567 A1, cited previously) and Baker et al. (US 2002/0091439 A1, cited previously). Weadock discloses a vascular device comprising a stentless bifurcated graft (10), a first docking head (20) at the proximal end of the graft, and second docking and third heads (50, 52) at the distal ends of the graft. Weadock does not disclose the exact structure of the docking heads claimed (conical). Elliot teaches in the same field of vascular devices, conical docking head structures (16+22) that seal and secure the graft to the vessel wall, the conical taper provides increased surface area with the vessel to improve the seal. Elliot's docking heads do not have inclined barbs. Baker teaches inclined barbs on vascular devices for attaching/fastening the graft to the vessel wall (195). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute Weadock's docking heads with those of Elliot's, as they are an obvious alternative for sealing grafts to vessel walls and combine the inclined barbs of Baker as such provide improved fastening to the vessel wall.

Claims 40 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner et al. (US 6,635,066 B2) in view of Fogarty (US 6,110,198, cited previously). Tanner discloses a vascular device substantially as claimed (see above). Tanner discloses a graft (110) and docking

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heads (20, 100), the docking heads made of graft material to seal against the vessel wall. Tanner does not disclose however the docking heads (conical grafts) to have slits. Fogarty teaches in the same field of vascular devices, the use of slits (162) on graft structures (fig.9a) in order to provide a flexible material that is expandable such that less material may be used to produce it, lowering costs (col.14, lines 30-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Tanner's vascular device having graft and end conical grafts (docking heads) with Fogarty's teaching of putting slits in the grafts in order to provide more flexible expandable docking heads at a lower cost.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755.

The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738